

The certification guidelines of Food and related product labeling, Promotion and Advertisement of Food Concerning Exaggeration Deception or Having Medical Efficacy

(Specific food ingredients can describe the physiological effects of sentence) Proposal Procedure

Specific Ingredient Name (Chinese): _____

Specific Ingredient Name (English): _____

Manufacturer or Association/Union/Institution: _____

Contact Person: _____

Address: _____

Telephone: _____

Email: _____

Date:

Instructions

1. Information on the use of the forms:

(1) The certification guidelines of Food and related product labeling, Promotion and Advertisement of Food Concerning Exaggeration Deception or Having Medical Efficacy (Specific food ingredients can describe the physiological effects of sentence) Proposal Procedure:

- A. The “recommended wording” shall not contain Exaggerated Misleading Information ,Medical Effects or any of the 13 Health Care Effects claims for Health Food Control Act.
- B. The “specific ingredient in a food product” refers to a specific ingredient fit for human eating and good for maintenance or improvement of physical health.
- C. The specific ingredient name should be provided in both Chinese and English.
- D. Use one proposal form for no more than one specific ingredient. Submit multiple proposal forms for recommendation of multiple specific ingredients.

(2) Form 1: A Literature Review Summary on Safety Assessments of a Specific Ingredient

The applicant shall use the form to provide a summary of the safety assessment literature review on the specific ingredient. The original assessments and studies referenced in the summary report must be submitted as appendices to the literature review summary form and arranged in the order of the “bibliographic reference number” assigned to each information source.

(3) Form 2: A Literature Review Summary on the Physiological Effects of a Specific Ingredient

The applicant shall use the form to provide a summary of the literature review on the physiological effects of the specific ingredient. The original assessments and studies referenced in the summary report must be submitted as appendices to the literature review summary form and arranged in the order of the “bibliographic reference number” assigned to each information source.

(4) Form 3: A Literature Review Summary on the Physiological Effects Claims of a Specific Ingredient Officially Approved by Foreign Governments

The applicant shall use the form to provide a summary of the literature review on the physiological effects claims of a specific ingredient officially approved by foreign governments. The original regulations and studies referenced in the summary report

must be submitted as appendices to the literature review summary form and arranged in the order of the “bibliographic reference number” assigned to each information source.

2. General Instructions

- (1) Directions Governing the Regulations of the Labeling, Promotion and Advertisement of Food Concerning Exaggeration, Deception or Having Medical Efficacy (Specific food ingredients can describe the physiological effects of sentence) Proposal Procedure is available online for download (website: <http://www.foodlabel.org.tw/FdaFrontEndApp/Law/Edit?SystemId=7ccd663e-ac75-4c64-9c38-3226636114b9&CIType=3&key=%E7%89%B9%E5%AE%9A>) Please produce your own forms in line with the format provided in the official proposal form if the latter does not provide sufficient space for your use.
- (2) The applicant shall key-in the required information on the form (software requirement: Microsoft Word; font: DFKai-SB; the font size may be adjusted according to needs), print out the filled form and put together in a loose-leaf binding. The document submission must include, in addition to the forms and documents, a CD that contains the electronic files of the former.
- (3) The documents, material and reference literature in support of the proposal shall be submitted in A4 size. Where the documents are larger than A4, fold the paper accordingly to ensure they are in the A4 size and arrange the bibliographic material as appendices to the proposal in the assigned order. Each page shall be assigned a page number for ease of access by reviewers.
- (4) The reference numbers assigned to the reference material listed in the literature review summary shall be identical with the bibliographic reference numbers assigned to the appendices to the proposal.
- (5) Any reference material written in a language other than Chinese and English must be accompanied by a Chinese translation. Reference material written in English shall be accompanied by a Chinese translation of selected crucial information. Applicants shall ensure the accuracy of the translations to avoid criminal charges and prosecution.

3. Contact person:

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<input type="checkbox"/> Manufacturer* <input type="checkbox"/> Association/union/institution*	Name		(Corporate Seal)	Address	
	Person-in-charge		(Personal Seal)	TEL	
<p>*Required documents:</p> <p>Manufacturer are required to provide a photocopy of the Certificate of Incorporation and Business Registration Certificate. Associations/unions/institutions are required to provide a MOI-issued Certificate of Incorporation.</p>					
Contact Person:		Address: Telephone: Email:			
Specific ingredient name (no more than one ingredient) Chinese name: English name:					
Recommended wordings:					
Date of proposal: _____ (year/month/day)					

Form 1: A Literature Review Summary on Safety Assessments of a Specific Ingredient

Reference No.	Reference literature Material name/source	Clinical Trial or Animal Testing Design				Test Outcome	Source: Web link
		Dose	Sample Size	Type	Test Duration		
1.1							
1.2							
1.3							
1.4							

Form 2: A Literature Review Summary on the Physiological Effects of a Specific Ingredient

Reference No.	Reference literature Material name/source	Clinical Trial or Animal Testing Design				Test Outcome	Source: Web link
		Dose	Sample Size	Type	Test Duration		
2.1							
2.2							
2.3							
2.4							

**Form 3: A Literature Review Summary on the Physiological Effects Claims of a Specific Ingredient Officially
Approved by Foreign Governments**

Reference No.	Country/Regulatory Agency	Date of Approval and Announcement (Year/month/day)	Specific Ingredient Name	Content Range	Physiological Effects Claim	Source: Web link
3.1						
3.2						
3.3						
3.4						